BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Root Cause Analysis, CAPA, and Compliance Writing (WORK-011)

OVERVIEW:

There have been several Form 483's and Warning Letters being issued to companies by the FDA as it relates to CAPA investigations because of insufficient or incomplete documentation of such investigation reports. All failures, deviations, complaints or out of specification investigations must be adequately documented, corrected, prevented and checked for effectiveness through the use of a compliant CAPA investigational system and program. The purpose of this workshop is to help authors and reviewers of CAPA investigation reports to improve the quality of their regulatory documents.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products in documenting their CAPA investigation reports in order to avoid FDA or other regulatory bodies' inspection findings in these areas. It will be a great resource to Quality Assurance, Manufacturing, Regulatory Affairs, Supplier Quality and Quality Control personnel and management within the Pharmaceutical, Biotechnology and Medical Device companies. Although the workshop focuses on writing effective CAPA investigation reports, it will also benefit any personnel who write other regulatory documents, such as SOPs, work instructions, policies, validation protocols, batch records, DMRs, and so on. Effective writing of those documents will avoid situations that could end up in opening CAPA investigations.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Compose an effective investigation report to optimize understanding and clarity
- Avoid writing errors

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course)

TRAINING DURATION:

14 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
1.4 CEUs for this program.
FULL attendance to the learning event
is mandatory to receive CEUs.

COURSE INSTRUCTOR:

Manuel E. Peña-Rodríguez is a process improvement and training consultant within the textiles, electronics, and FDA-regulated industries with more than 20 years of experience in those fields. Since January 2006, he is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training and implementation of Lean Six Sigma initiatives and CAPA / Root Cause Analysis workshops. He also serves as professor in the graduate program in biochemistry at the University of Puerto Rico, Medical Sciences Campus, in San Juan. Manuel received his J.D. degree from the Pontifical Catholic University of Puerto Rico and his master's of engineering in Engineering Management from Cornell University in Ithaca NY. He is also a licensed Professional Engineer registered in Puerto Rico. Manuel is an ASQ Certified Six Sigma Black Belt, Manager of Quality & Organizational Excellence, Quality Engineer, Quality Auditor, Biomedical Auditor, and HACCP Auditor. He is also a Senior member of ASQ and former Chair of the Puerto Rico ASQ Section. He is the author of the book "*Statistical Process Control for the FDA-Regulated Industry*", published by ASQ Quality Press in April 2013 and co-author (with José Rodríguez-Pérez) of the article "*Fail-Safe FMEA*" published in the January 2012 edition of the ASQ Quality Progress magazine.

Solmarie Vélez Rivera is a training consultant within the FDA-regulated industries with over 20 years of experience. She has a Bachelor Degree in Industrial Engineering from the University of Puerto Rico at Mayaguez Campus. She also has a Master Degree in Business Adminitration from University of Phoenix, Puerto Rico Site. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on ASQ Certified Quality Auditor Academia, Internal Audits Program, Quality Systems Regulations (21CFR820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor, Manager of Quality & Organizational Excellence, Biomedical Auditor, and HACCP Auditor.

Gloryvee Maldonado Pérez is a training consultant within the FDA-regulated industries with more than 10 years of pharmaceutical and medical devices industry experience, in the areas of quality assurance, quality control, regulatory, validation, manufacturing, and packaging. She has a Bachelor Degree in Chemistry from the University of Puerto Rico at Rio Piedras Campus. She also has a Master of Science in Manufacturing Competitiveness, with a specialization in pharmaceutical products, from the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She is an ASQ Certified Six Sigma Black Belt, and Certified Quality Engineer. She is also a CAPA System Expert Investigator and ISO 13485 Lead Auditor.

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Passion for Quality

Title: Root Cause Analysis, CAPA, and Compliance Writing (Day 1)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 9:00	**Opening Remarks**
9:00 – 10:15	**Introduction** • The Vicious Cycle • Root Cause Identification • The Correct CAPA System Flow • The Closed-Loop CAPA Process • Feeders of the CAPA System • Key Definitions of the CAPA System • Risk Prioritization of Investigations
10:15 – 10:30	**Break**
10:30 – 12:00	**Root Cause Analysis** • The Investigation Report • Causal factors and root causes • Problem Description • Chronology of events
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Root Cause Analysis (cont.)** • Comparative analysis: Is/Is not matrix • Flowchart: Task analysis • Change analysis **Break-Out Session:** Writing an Effective Problem Statement
15:00 – 15:15	**Break**
15:15 – 17:00	**Root Cause Analysis (cont.)** • Barrier Analysis • Cause and Effect Analysis • FTA (Fault Tree Analysis) • Determining the probable root cause(s) • Root causes classification

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Root Cause Analysis, CAPA, and Compliance Writing (Day 2)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 10:15	**Effective CAPA** • Problem Detection • The CAPA Plan • Effectiveness Evaluation • Eleven Biggest CAPA Opportunities • CAPA Effectiveness Examples
10:15 – 10:30	**Break**
10:30 – 12:00	**Break-Out Session:** Writing an Effective CAPA Effectiveness Verification Statement
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Compliance Writing** • Introduction • Measures of Excellence • Documentation Style Manual
15:00 – 15:15	**Break**
15:15 – 16:00	**Compliance Writing (cont.)** • Documentation Style Manual • Writing for Effectiveness
16:00 – 17:00	**Post-Test**